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FEB 15 2001

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Inventor : W. Roy KNOWLES, M.D.
5 Filing Date: 19 July 2000
Ser. No.: 09/619,142
Art Unit: 1614
Examiner: Vickie KIM



Handwritten signature and date: 2-21-01

RESPONSE

I. §112 REJECTIONS

Claim 12 stands rejected as omitting the term
"method." Examiner correctly assumes that before "for," the
correct term would be "method." Applicant requests Examiner
15 enter an Amendment to correct the informality.

II. THE PRIOR ART REJECTIONS

All claims stand rejected under either §102 or
§103. Before addressing the specific rejections, we will
first give brief tip of the hat to summarize the prior art,
20 and briefly discuss how the claimed invention turns the
teaching of the art on its head. Then, we will turn to the
specific rejections.

A. The Art Teaches Away from The
Claimed Combinations

25 The prior art of record teaches how to use
penetration enhancers, minoxidil or progesterone separately.
The art, however, teaches away from combining these. This is
due to the assumption that combining minoxidil (or

progesterone) with a penetration enhancer would make the minoxidil (or progesterone) penetrate into the **systemic blood circulation** and create adverse **systemic side effects**.

Knowles, W.R., Rule 132 Declaration.

5 Dr. Knowles has turned this conventional wisdom on its head. He has found that, contrary to the teachings of the art, a penetration enhancer does not create unwanted systemic side effects - if used properly.

B. \$102 Rejections

10 1. Bradbury

Claims 1-4, 8-15, 19-22 stand rejected as anticipated under \$102(e) by Bradbury. Bradbury does not anticipate the claims, because (a) Dr. Knowles antedates Bradbury, (b) Bradbury does not enable one of skill in the art to practice Dr. Knowles' invention, and (c) Bradbury teaches away from Dr. Knowles' combinations.

a) *Applicant Antedates Bradbury*

Applicant conceived of his invention before

Bradbury's July 17, 1998 filing date. See Knowles, Rule 131 Declaration. Thus, Bradbury must be withdrawn as a reference.

b) *Bradbury Requires Undue Experimentation*

Bradbury discloses millions of potential combinations. See Knowles, W.R., Rule 132 Declaration.

Discerning which one of these millions of possible combinations would make Dr. Knowles' invention, would take years of research. Id.

This is "undue experimentation." The Federal
5 Circuit recently said that even if there are far fewer potential combinations, the reference must "single out particular" combinations, to enable them:

10 It is an old custom in the woods to mark trails by making blaze marks on the trees. It is of no help in finding a trail or in finding one's way through the woods . . . to be confronted simply by a large number of unmarked trees. **We are looking for blaze marks which single out particular trees.** We see none.

15 Purdue Pharma L.P. v. Faulding Inc., slip op. 99-1416 (Fed.Cir. Oct. 25, 2000) (emphasis added), quoting In re Ruschig, 379 F.2d 990 (CCPA 1967). The Federal Circuit further cautioned, "the blaze marks directing the skilled
20 artisan to that tree **must be in the originally filed disclosure.**" Id. (emphasis added). Here, Bradbury has no "blaze marks" singling out or directing the skilled artisan through the millions of possible combinations to Dr. Knowles' specific invention.

25 Because Bradbury requires undue experimentation, it cannot anticipate. See Biogen, Inc. v. Amgen, Inc., 973 F.Supp. 39 (D.Mass. 1997).

c) *Bradbury Teaches Away from the
Claimed Invention*

Unlike Dr. Knowles, Bradbury says hair loss

preparations need lupane triterpines. By so doing, Bradbury

5 actively teaches away from Dr. Knowles' invention. See
Knowles, W.R., Rule 1.132 Declaration.

2. Bazzano

Claims 1-4, 8-15, 19-22 stand rejected as
anticipated under §102(b) by Bazzano.

10 For Bazzano to "anticipate" the claims, however, it
must do two things: it must disclose every element of the
claimed invention, and it must enable practicing the
invention. Akzo N.V. v. U.S. Intern. Trade Comm'n., 808 F.2d
1471 (Fed.Cir. 1986), cert. denied, 482 U.S. 909. Bazzano
15 does neither.

a) *Bazzano Does not Disclose Every
Claim Element*

Dr. Knowles claims minoxidil + penetration
enhancer. In contrast, Bazzano discloses minoxidil +
20 retinoid. The Office Action acknowledges that Bazzano lacks
this element, but says "penetration enhancer ... is not
considered to be critical."

Reconsideration is requested, because penetration
enhancer is an express, "essential" claim element. See
25 Knowles, W.R., Rule 1.132 Declaration. The Examiner cannot

simply ignore certain claim elements that do not exist in the reference. Because the reference does not disclose **every** claim element, it cannot anticipate. *E.g., Akzo, supra; Multi-Tech Systems, Inc. v. Hayes Microcomputer Prods., Inc.,*

5 800 F.Supp. 825 (D.Minn. 1992), *appeal dismissed*, 988 F.2d 130.

Furthermore, combining minoxidil or progesterone with penetration enhancer has apparently **never** been "utilized by the skilled artisan," much less in "common practice." See
10 Knowles, W.R., Rule 1.132 Declaration.

b) *Bazzano Teaches Away From The Claimed Invention*
Bazzano says that without retinoid, minoxidil just does not work. Bazzano thus teaches away from the claimed
15 invention. See Knowles, W.R., Rule 132 Declaration.

C. \$103 Rejections

Claims 1-22 stand rejected under \$103(a) over Hoke in view of Orentreich. Hoke cannot render the claims obvious, because (1) Dr. Knowles antedates Hoke, (2) the art
20 provides no suggestion to combine Hoke and Orentreich (and in fact teaches to not combine), (3) the combination lacks an essential claim element, and (4) the claimed invention shows secondary indicia of non-obviousness.

1. Applicant Antedates Hoke

Applicant conceived of his invention before Hoke's filing date. See Knowles, W.R., Rule 1.131 Declaration.

Thus, Hoke must be withdrawn as a reference.

5 2. The Art Teaches Away From
Combining the References

A "claimed invention is not obvious solely because it is composed of elements that are all individually found in the prior art." Life Technologies, Inc. v. Clontech Laboratories, Inc., slip op. 99-1550 (Fed. Cir. Sept. 21, 2000). Rather, the prior art must show "a reasonable expectation of success" in making the combination. Id. The Federal Circuit says:

15 Virtually all inventions are combinations of old elements. Therefore, an examiner or accused infringer may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few
20 patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner or accused infringer to use the claimed invention
25 itself as a blueprint for piecing together elements in the prior art . . . To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis.

30 Yamanouchi Pharmaceutical Co., Ltd. V. Danbury Pharmacal Inc., slip op. 99-1521 (Fed.Cir. Nov.2000).

Thus, the references may be combined only if there is a suggestion or motivation to do so **in the prior art**. In other words, somewhere **in the prior art**, someone must say, "you should combine Hoke with Orentreich to get Knowles."

5 Here, there is none. On the contrary, the prior art **discourages** combining the references, due to the components' "well documented" adverse side effects. See Knowles, W.R., Rule 132 Declaration.

10 3. The Cited Combination Lacks An Essential Claim Element

The cited combination lacks an express, "critical" claim element - penetration enhancer. Knowles, W.R., Rule 132 Declaration. Because the combination does not disclose **every** claim element, the combination cannot anticipate.

15 E.g., Akzo, supra; Multi-Tech Systems, Inc. v. Hayes Microcomputer Prods., Inc., 800 F.Supp. 825 (D.Minn. 1992), appeal dismissed, 988 F.2d 130.

20 4. The claimed invention shows secondary considerations of non-obviousness

The claimed invention shows many indicia of non-obviousness: solving a long-felt need, others' failure to solve the problem, and unexpectedly synergistic results.

The claimed combination solves a long felt need for
25 a solution to a hairy, difficult problem. Knowles, W.R.,

Rule 132 Declaration. Solving such a long-felt need weighs against obviousness. B.F. Goodrich Inc. v. Aircraft Braking Systems Corp., 72 F.3d 1577 (Fed.Cir. 1996).

Dr. Knowles succeeded where others failed.

5 Knowles, W.R., Rule 132 Declaration. Dr. Knowles' success, where others had failed, shows his solution is not obvious. B.F. Goodrich Inc. v. Aircraft Braking Systems Corp., 72 F.3d 1577 (Fed.Cir. 1996).

Dr. Knowles' results were unexpectedly superior.

10 Knowles, W.R., Rule 132 Declaration. A claimed compound's unexpectedly superior activity rebuts obviousness. In re Chupp, 816 F.2d 643 (Fed.Cir. 1987).

III. SUMMARY

15 A. Declarations
The prior art of record neither enables nor contains every element of Dr. Knowles' invention. The references thus cannot anticipate it. Reliance on Dr. Knowles' Rule 131 Declaration is thus believed unnecessary; accordingly, it will be assumed that the Rule 131 Declaration was not relied upon, unless Examiner indicates how the art of record enables the claims, and where the prior art of record discloses the claim limitation "penetration enhancer."

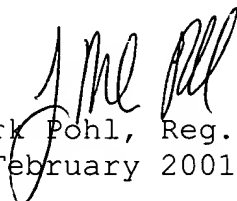
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B. Affidavit of References

Applicant respectfully requests Examiner to provide
an Affidavit of References providing evidence of the factual
assertions recited in the Office Action at page 3, line 16;
5 page 4, lines 20-22; and page 5, lines 1-2, lines 3-4, and
lines 7-8.

Respectfully submitted,

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8 February 2001

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